PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Shah et al.

Serial No.: 09/891,983

Filed: June 26, 2001

For: METHODS FOR THE SIMULTANEOUS DETECTION OF HCV ANTIGENS AND HCV ANTIBODIES

Case No.: 6821.US.01

Examiner: Wortman, D.

Group Art Unit: 1648

Certificate of Mailing under 37 CFR §1.8(a): I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the:

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Date of Deposit: 1-15-04
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DECLARATION UNDER 37 C.F.R. § 1.131

Commissioner for Patents
P.O. Box 1450
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Sir:

We, DINESH O. SHAH, GEORGE J. DAWSON, A. SCOTT MUERHOFF, LILY JIANG, ROBIN A. GUTIERREZ, THOMAS P. LEARY, SURESH DESAI AND JAMES L. STEWART, citizens of the United States of America and residents of either Illinois or Wisconsin, do declare and say that:

We are co-inventors of the above-referenced application for patent filed on June 26, 2001.

In the Office Action of April 29, 2003, claims 13 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Chien et al. (U.S. Patent Publication No. 2002/0192639

A1). Additionally, claims 13 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Bahl et al. (U.S. Patent Publication No. 2003/0049608 A1). Further, claims 13 and 14 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Aoyagi et al. (U.S. Patent Publication No. 2002/0173493 A1). Additionally, claims 8-11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoyagi et al. (U.S. Patent Publication No. 2002/0173493 A1). Further, claims 8-11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chien et al. (U.S. Patent Publication No. 2002/0192639 A1). Also, claims 8-12, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bahl et al. (U.S. Patent Publication No. 2003/0049608 A1) in view of Chien et al. (U.S. Patent Publication No. 2002/0192639 A1).

We, conceived and reduced to practice, in the United States, the invention claimed in claims 13 and 14 prior to the priority date (i.e., the date of filing of the provisional application) of Chien et al. (i.e., June 15, 2000), prior to the priority date (i.e., the date of filing of the provisional application) of Bahl et al. (i.e., March 28, 2001) and prior to the filing date of Aoyagi et al. (i.e., April 26, 2002). Further, we conceived and reduced

to practice, in the United States, the invention claimed in claims 8-11 and 15 prior to the filing date of Aoyagi et al. (i.e., April 26, 2002) and prior to the priority date of Chien et al. (i.e., June 15, 2000). Additionally, we conceived and reduced to practice, in the United States, the invention claimed in claims 8-12, 14 and 15 prior to the priority date of Bahl et al. (i.e., March 28, 2001) as well as Chien et al. (i.e., June 15, 2000). These assertions are evidenced by the following:

Attached Exhibit A illustrates that, prior to June 15, 2000 (i.e., the priority date of Chien et al. and the earliest date of the documents cited above), we developed a method for the simultaneous detection of HCV antigens and HCV antibodies in a test sample. In particular, as evidenced by Exhibit A, in one embodiment, the HCV antigens were to be captured on a solid phase, and then the captured antigens were be detected with an antibody (e.g., monoclonal antibody) labeled with a reporter molecule. Further, the solid phase was to be coated with various HCV proteins (e.g., NS3, NS4 and fragments of the core protein) in order to capture HCV antibodies. The antibodies would then be recognized by a second antibody (e.g., goat anti-human IgG) labeled with a reporter molecule.

Further, Exhibit A also illustrates a schematic view of the assay. In particular, the figure establishes how the antibodies in the test sample are to be detected as well as how the core antigens are to be detected using conjugated monoclonal antibodies.

Exhibit B illustrates that prior to the June 15, 2000 priority date of Chien et al., we carried out the assay and obtained positive data. In particular, Exhibit B illustrates various reagents used in the assay (i.e., those coated on the solid phase) and evidences that upon running the assay, results were obtained indicating that one could detect HCV antigen and HCV antibody simultaneously in a sample.

In summary, the attached Exhibits establish that the claimed invention was conceived of and reduced to practice, prior to the priority date of Chien et al. (i.e., June 15, 2000) as well as the subsequent dates of Bahl et al. and Aoyagi et al.

Although all the dates on Exhibits A and B have been blocked out, such dates are prior to June 15, 2000.

We declare further that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that

willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant application or any patent issuing thereon.

Respectfully submitted,

1) _____
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Date: Jan 7, 2004

2) _____
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3) _____
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8) _____
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